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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,329	02/08/2001	Philip C. Gevas	ACG2AUSA	4824

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/03/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/700,329

Applicant(s)  
Gevas et al.

Examiner  
Michael Borin

Art Unit  
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 25, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7 and 15-43 is/are pending in the application.
- 4a) Of the above, claim(s) 7, 19-23, and 30-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-18 and 24-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8, 15, 1 6) ☐ Other:

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## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 7,15-43 are pending.

Response to restriction requirement filed 03/18/2002 is acknowledged. Applicant elected, without traverse, Group III, claims 15-18, 24-29. Claims 7,19-23, 30-43 are withdrawn from consideration, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 7,19-23, 30-43 is requested.

In response to election of species requirement, applicant elected species of G17 peptide SEQ ID No. 1. Claims 15-18, 24-29 are addressed to the extend they read on the elected species.

### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statements , papers #7,8,15,17, have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

### ***Sequence Listing***

3. The Sequence Listing was approved by STIC for matters of form.

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***Claim Rejections - 35 USC § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103<sup>c</sup> and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 15-18,29 are rejected under 35 U.S.C. 102(b) as anticipated by Watson et al (Cancer Research, 1996, or Int. J. Cancer, 1995; references AS and AR, respectively) or Gevas et al (US Patent 5,607,676).

The instant claims, to the extent they read on the elected species, read on method for treating hypergastrinemia by administering an immunogenic composition comprised of a G17 fragment SEQ ID No. 1 (which is nine N-terminal residues of gastrin) linked to an immunogenic carrier.

Watson et al.,1995 and 1996 references, teach immunogen, Gastrimmune, which is composed of nine N-terminal residues of gastrin linked to immunogenic carrier, such as diphtheria toxoid. This composition was used in rising anti-G17 antibodies; the later reduced gastrin level *in vivo*.

Gevas et al (US Patent 5,607,676<sup>1</sup>) teaches teach composed of G17 fragments, such as nine N-terminal residues of gastrin (e.g., col. 5, line 50), linked to immunogenic carrier, such as diphtheria toxoid. Said immunogen generates anti-gastrin antibodies which reduce level of gastrin and inhibit hypergastrinemia related disorders.

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<sup>1</sup>as well as other US patents of these applicants (Gevas et al. are the inventors of the instant invention as well) listed in Information Disclosure Statement filed 03/20/2001.

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It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed or fully envisioned by the teaching of the references cited above.

5. Claims 24-28 are rejected under 35 U.S.C.103(a) as obvious over by Watson et al (Cancer Research, 1996, or Int. J. Cancer, 1995; references AS and AR, respectively) or Gevas et al (US Patent 5,607,676) and further in view of Sundler, F. Acta Oncologica, 1991 30 (4) 419-27.

The instant claims are drawn to method addressed above wherein, in addition, other anti-gastrin agents are used. Modification to combine pharmaceutical agents, all known to be useful is anti-gastrin therapy, would have been obvious to one of ordinary skill in the art in view of the fact that the courts have held that "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be useful for the very same purpose". See In re Sisi, 169 USPQ 423, 426 (CCPA 1971). Because combination therapies are well-known in the art and because it would have been desirable to use plural therapies in order to maximize the effectiveness of, in this instance, anti-gastrin therapy, it would be *prima facie* obvious to one of ordinary skills in the art at the time the invention was made to be motivated to use the anti-gastrin

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immunogen of the instant invention not only as a sole active pharmaceutical agent, but also in combination with other known inhibitors of acid production, such as, for example, omeprazole or ranitidine. See, for example, Gevas , col. 1, lines 43-45 or abstract of Sundler et al. Selection of such acid production inhibitors would be obvious for an artisan.

***Conclusion.***

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 1, 2003

mlb

MICHAEL BORIN, PH.D.  
PRIMARY EXAMINER

